## REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated May 20, 2004.

### *Status of the Claims*

Claims 1-4, 9-14 and 9-22 are pending in the application. Claim 19 has been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended claims can be found generally through Applicants' specification.

### *The Double Patenting Rejections*

Claim 19 is rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,591,629 ("the '629 Patent"). The Examiner asserts that the monoclonal antibody of the issued '629 Patent anticipates claim 19. Applicants respectfully disagree. Claim 19 refers particularly to a synthetic autoantibody as above clarified by amendment. Applicants again point out that "synthetic autoantibody capable of inducing remyelination of central nervous system axons" refers to an autoantibody made by a synthetic process, including wherein elements are combined to form a coherent whole, particularly as described in the Specification, including at page 42, lines 18-19, a monoclonal antibody that is genetically altered. Synthetic autoantibody thus includes: autoantibody prepared synthetically by recombinant means known to the skilled artisan, recombinant generation of antibodies being a known generic technique (page 8, lines 18-19); humanized antibody, for instance, by the substitution of the human antibody nucleotide sequences in non-variable region of the murine mAb to reduce immunogenicity (page 42, lines 19-20); an antibody molecule having a plurality of antibody combining sites, each immunospecific for a different antigen (page 9, lines 20-23); bi-specific (chimeric) autoantibodies (page 8, lines 15-19); and autoantibodies including other functionalities, including suiting them for additional diagnostic use conjunctive with their capability of modulating - activity stimulating the remyelination of CNS axons (page

8, lines 20-23. The particular and specific hybridoma claimed in claim 1 of the '629 Patent does not anticipate or make obvious the patentable synthetic autoantibody(ies) of instant claim 19. Applicants respectfully request that the Examiner withdraw this rejection.

***The Specification Fully Enables the Claimed Invention***

The Examiner has rejected claims 1-4, 9-14 and 19 under 35 U.S.C. 112, first paragraph, because the Examiner asserts that the specification, while being enabling for methods for stimulating remyelination or treating a demyelinating disease in a mammal by administering an effective amount of monoclonal antibodies that induce remyelination of the CNS, the specific monoclonal antibody SCH79.05 and synthetic monoclonal autoantibodies, it does not reasonably provide enablement for the specific monoclonal autoantibodies A285, 01, 04, HNK-1 and synthetic autoantibodies. The Examiner asserts, despite Applicant evidence and arguments, that the antibodies A2B5, HNK-1, 01 and 04 are not publicly available for human and pharmaceutical use. In prior actions, the Examiner alleged that these antibodies were not publicly available per se. Applicants have prior presented evidence indicating that each and any of these antibodies can be obtained and/or are for commercial sale to the public. In this Action, however, the Examiner now asserts that the antibodies, while available, are "restricted and not available for the claimed use or pharmaceutical composition". The Examiner remarks that the ATCC™ requires a Material Transfer Agreement and that the ATCC™ products are restricted in use and practice. Applicants do not disagree that the ATCC™ is in the business of providing research grade products and materials and is not a pharmaceutical manufacturer. Most if not all of the ATTC™'s hybridoma and cell line products are not intended for use in humans, although use in laboratory research, including in other animals and mammals, for instance animal model systems, is permitted. Applicants' agent randomly selected a dozen antibodies or hybridomas from the ATTC™'s online catalog and the catalog detail for each and every one referred to a Material Transfer Agreement and stated intended for laboratory research and not intended for use in humans. Therefore, Applicants would assert that these antibodies are available and <u>can</u> be used in mammals, including for the claimed methods of remyelinating. It is not unusual for an applicant to discover a new use for a previously known compound that is patented by a third

party or for sale by a third party for a different pharmaceutical use. Applicants submit that it is not within the purview of the Examiner to determine whether an Applicant has the freedom to operate for such use or whether a license may or may not be required to commercially sell said product for the claimed use. This is a business operation issue and does not relate to patentability if the use is novel and nonobvious. Applicants assert that the antibodies for use in the methods are publicly available and that the methods can be performed and tested by the skilled artisan, even if in a research and non-human format. The actual commercialization of certain of these antibodies for therapy in humans is not relevant for patentability.

In view of the foregoing remarks, Applicants submit that the Examiner's rejection under 35 U.S.C. 112, first paragraph may properly be withdrawn.

***The 102(b) Rejection***

The Examiner has maintained her rejection of claim 19 under 35 U.S.C. 102(b) as being anticipated by Abo et al [J. Immunol. 127:1024-1029, 1987] or American Type Culture Collection, 1992, page 435. The Examiner asserts that the HNK-1 antibody factually anticipates the pharmaceutical composition of claim 19, stating that the Specification teaches that the HNK-1 antibody is a natural autoantibody and that Applicants have "merely discovered a new use of an old composition". Applicants agree that the use of the HNK-1 antibody and its capacity for stimulating remyelination of CNS axons in a mammal as discovered, disclosed and claimed by Applicants is new and novel, however Applicants disagree that a new use of an old composition is anticipated by the original composition itself. Applicants further submit that the HNK-1 antibody hybridoma does not anticipate claim 19, which is directed against a synthetic autoantibody composition. As detailed above, "synthetic autoantibody capable of inducing remyelination of central nervous system axons" refers to an autoantibody made by a synthetic process, including wherein elements are combined to form a coherent whole, particularly as described in the Specification, including at page 42, lines 18-19, a monoclonal antibody that is genetically altered. The particular and specific HNK-1 hybridoma does not anticipate or make obvious the patentable synthetic autoantibody(ies) of instant claim 19. Applicants respectfully

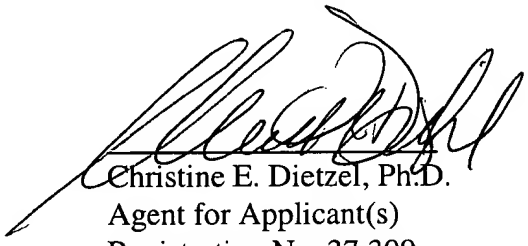
request that the Examiner withdraw this 102 (b) rejection.

## CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

KLAUBER & JACKSON



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